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Award Number: W81XWH-11-1-0841

TITLE: National Trauma Institute: A National Coordinating Center for Trauma Research Funding

PRINCIPAL INVESTIGATOR: Donald Jenkins, M.D.

CONTRACTING ORGANIZATION:
National Trauma Institute

San Antonio, TX 78230

REPORT DATE: October 2013

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REPORT DOCUMENTATION PAGE

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this grant is to support a national coordinating center for trauma research funding, and provide a forum for dissemination of trauma research information. The infrastructure/process is streamlined and efficient leading to the selection of research projects based on a solid scientific, peer review of submitted research proposals and subsequent conduct of important clinical trauma research that will impact patient outcomes.

15. SUBJECT TERMS
Trauma, ICU, education, research, training, analysis, practice

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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INTRODUCTION

The National Trauma Institute (NTI) proposed to utilize $3,845,000 in congressional funding to continue and broaden work begun by NTI in previous congressional special interest funding proposals. NTI's objective is to distribute and manage funding for peer-reviewed research projects for areas of greatest impact in trauma, in order to change practice to save lives and improve outcomes for those affected by trauma, and to disseminate research findings to the trauma community.

BODY

Statement of Work

A. The contract will support a national coordinating center for trauma research funding.

1) Requests for proposals (RFP) based on areas of scientific merit in trauma and emergency or critical care will be prepared and issued.

2) NTI Board Science Committee will score proposals according to scientific merit, clinical impact, ability to perform the research, innovation, and military relevance

.

3) NTI Board will update trauma research subject areas based upon the impact on survival or care of patients, existing funding, and funding availability annually.

4) NTI will perform Award management and compliance to include all appropriate USAMRMC HRPO requirements.

5) NTI will provide research funding for proposals that seek to address areas of urgent need in the treatment of trauma.

B. The contractor will provide multiple meeting forums for progress towards methods for military-civilian transfer of medical advances, and development of clinical protocols from promising currently funded pilot studies, as determined by the Science Committee. These meetings will include military and civilian researchers.

A. National Coordinating Center for Trauma Research Funding.

Tasks 1-3: Requests for proposals, scientific peer review, and update trauma research subject areas

Tasks 1-3 are complete and details were reported on previous reports.

NTI Board meetings occur every two months. These are the forums where updates to trauma research subject areas based upon the impact on survival or care of patients, existing funding, and funding availability is discussed.

Task 4-5: Perform Award management and compliance to include all appropriate USAMRMC HRPO requirements and provide research funding.

There are 9 research projects, including the Delayed Splenic Rupture after Non-Operative Management of Blunt Splenic Injury (PI: Dr Ben Zarzaur). The latter is an American Association for the Surgery of Trauma (AAST) Multi-Institutional Prospective Trial and has eleven research sites. NTI subcontracted with each participating site for this award only. Therefore, there were a total of 19 research subcontracts to be executed. Subcontracts are not executed until the site has obtained HRPO approval. Subcontracts with all 19 of the research sites have been completed.

Upon local IRB approval, all required documents are submitted to HRPO for approval. Throughout the research study, HRPO compliance is maintained through regulatory compliance activities. Throughout the research study, all regulatory compliance activities, such as amendments, continuing reviews, protocol deviations, adverse events, study close out upon study completion are managed per the guidelines set forth by the HRPO.

An eighteen month No Cost Extension for the overall contract between NTI and USAMRMC was approved. The current ending date is March 28, 2014.

Project 1:
Project Title: Acute Lung Injury Ventilation Evaluation (ALIVE) Trial
Principal Investigator: Suresh Agarwal, MD
Lead site: Medical College of Wisconsin.
Participating Sites: Boston Medical Center (BMC), San Antonio Military Medical Center (SAMMC), Massachusetts General, University of Maryland Medical Center, University of Mass Memorial Medical Center, University of Penn, Harborview Medical Center, and University of Texas Health Science Center at San Antonio (UTHSCSA)
Lay Abstract: Acute lung injury (ALI) from treatment of patients with severe injuries remains a significant healthcare burden for both the military and civilian populations. It accounts for over 75,000 deaths annually, is associated with numerous complications to the lungs and other organs, and places a considerable financial burden upon the healthcare system. Many studies have attempted to demonstrate techniques to treat ALI. However, these have met with extremely limited success and still result in mortality in 30-40% of those afflicted. Mechanical ventilation (respirator) techniques remain the only accepted treatment therapy of these patient groups, but these are also associated with problems including segmental lung collapse, increased time on the ventilator, and increased incidence of pneumonia. Novel, non-experimental, therapies of managing ventilators exist but have not been compared with traditional therapy in regards to management of patients with ALI. One method, airway pressure release ventilation (APRV), provides greater patient respiratory control, better oxygenation, less sedative use, and decreased incidence of pneumonia. This proposed study is a randomized examination of biomarkers of patients with ALI using two ventilator modes: APRV and ARDSNet (traditional modality for management of ALI). Our long term goal is to improve health outcomes of patients with ALI and ARDS and gain a better understanding of its pathogenesis, prevention, and treatment.
Progress Reported: *HRPO Log #A-16977.6.* Due to the Principal Investigator's relocation, the lead site changed from Boston Medical Center to the Medical College of Wisconsin and Boston Medical Center was retained as a participating site. NTI was notified of this move and lead site change in July 2012. Prior to this notification all IRB approved documents from Boston Medical

Center were submitted to HRPO on 10/11/11. HRPO recommendations for revisions were received on 3/6/12 and the recommended revisions were made. Once IRB approval was obtained at the Medical College of Wisconsin, all documents were submitted to HRPO for review and approval. HRPO approval was obtained on 9/5/13. The NTI Science Committee has expressed concern to the PI about the ability to complete this study within the specified timeframe, considering there are seven other participating sites. Each of these sites will also need to undergo HRPO review and approval. NTI will continue to monitor this project's process.

Project 2:
Project Title: The Safety and Efficacy of Platelet Transfusion in Patients Receiving Antiplatelet Therapy that Sustain Intracranial Hemorrhage
Principal Investigator: Mark Cipolle, MD
Lead Site: Christiana Health Care System, Newark DE
Lay Abstract: Brain hemorrhage is the most important reason for death and disability after injury or stroke. Many patients at this site are using antiplatelet medications that inhibit the early steps in blood clotting. While these medications are very effective in reducing the risk of heart attack and stroke, bleeding is an important side effect. While these medications do not cause brain hemorrhage, it is likely that they worsen a hemorrhage once it has occurred. In this first year this site plans to perform a pilot trial of 40 patients at our center in preparation of performing a multicenter, randomized, controlled clinical trial to test the potential benefit and safety of providing a platelet transfusion to patients suffering a brain hemorrhage while taking antiplatelet medication. Patients on antiplatelet therapy that have a brain hemorrhage seen on Computed Tomography (CT) scan within 4 hours of injury or onset of symptoms will be eligible. They will then be randomized (coin flip) to receive either a platelet transfusion or an infusion of salt water (control). Another CT scan will be obtained in 24 hours and we will compare the change in hemorrhage between groups. Other outcome measures tracked will be improvement in neurologic outcome and the development of a new heart attack, stroke or blood clot out to 90 days. We will also examine platelet function in all patients using a bedside test. An institutional review board and data safety monitoring board will oversee the trial to ensure patient safety.
Progress: *HRPO Log #A-16977.5*. This project was approved by HRPO on 4/4/12. Two quarters of subject enrollment was completed with 198 subject screened and two subjects were enrolled. The inclusion criterion of "traumatic brain hemorrhage only" impacted the number of eligible subjects. Dr Cipolle voluntarily closed this study due to difficulty in meeting his enrollment goals. Close out documents were submitted and approved by HRPO on 7/29/13.

Project 3:
Project Title: Transfusion of Stored Fresh Whole Blood (FWB) in a Civilian Trauma Center: A Prospective Evaluation of Feasibility and Outcomes
Principal Investigator: Henry Gill Cryer, MD
Lead Site: University of California, Los Angeles (UCLA)
Lay Abstract: Resuscitation protocols for trauma patients presenting with significant bleeding utilize administration of components of blood including Red Blood Cells (RBCs), plasma, and platelets. Despite improvements in emergency surgery and critical care, trauma patients with severe bleeding still suffer from high incidence of complications and death compared to patients that require fewer or no transfusions. Recent studies from military centers indicate that transfusion of Fresh Whole Blood may be more beneficial than individual blood components in patients with

severe hemorrhage. This has not been studied in civilian trauma patients mainly due to the technical difficulties and costs. This site proposes a feasibility and hospital outcomes study using FWB (storage time of 5 days) for resuscitating trauma patients with significant bleeding. A cohort of adult trauma patients presenting with severe hemorrhage and receiving resuscitation with FWB will be prospectively compared to a control group of patients receiving standard component therapy. The shelf-life of whole blood cost of treatment, levels of clotting and inflammatory markers in patient's blood samples, as well as the incidence of persistent bleeding, development of blood clots, infections, and mortality will be compared between the two groups. This study is designed to determine whether FWB transfusions are feasible in a civilian trauma center and to determine whether resuscitation using FWB is superior to component therapy in patients with severe hemorrhage.

Progress Reported: *HRPO log #A-16977.1.* HRPO approval was received on 3/6/2012. Subject enrollment is complete and analysis is in process/being finalized. The investigator is in the process of completing the final report. All outcomes will be reported in the next quarterly report.

Project 4:

Project Title: Detection and Management of Non-Compressible Hemorrhage by Vena Cava Ultrasonography

Principal Investigator: Jay Doucet, MD

Lead Site: University of California at San Diego (UCSD)

Participating Sites: University of Utah, Emory University, and University of Maryland School of Medicine.

Lay Abstract: This is a study of patients admitted with major traumatic injuries admitted in shock otherwise known as low blood pressure. Such patients may develop inadequate circulation to the organs as a result of internal blood loss. Early detection of internal blood loss can be difficult as physical examination alone may not detect significant internal blood loss. After traumatic injury, some patients with bleeding will develop shock. The inferior vena cava is the large vein draining blood from the lower body to the heart. The inferior vena cava stores blood and is known to empty when the patient has had significant blood loss. The vena cava diameter can be seen using ultrasound. This study intends to perform ultrasound to examine the vena cava diameter on patients just after arriving at a Trauma Center with major trauma and shock before and after giving fluids. This site proposes that measuring the inferior vena cava in this manner can predict those patients who are likely to continue bleeding and require interventions such as surgery. Early detection in these patients may avoid delays in treatment, complications and excess mortality. Because this examination is done with handheld ultrasound machines, it could be done outside hospitals and in military combat casualty care.

Progress Reported: *HRPO Log#A-16977.2a*. HRPO approval of the lead site was received on 11/17/2011 and all participating sites have also obtained HRPO approval. As of the last report dated 8/20/2013, all sites are screening subjects with two sites having enrolled (UCSD & Utah) twenty subjects. Total enrollment goal is 396 across all sites, about 33 subjects from each site. Subject screening and enrollment remains ongoing across all sites.

Project 5:

Project Title: Methicillin-Resistant Staphylococcus aureus in a Trauma Population: Does Decolonization Prevent Infection?

Principal Investigator: Robert Maxwell, MD

Lead Site: University of Tennessee Health Science Center at Chattanooga
Participating Sites: University of Tennessee Health Science Center at Memphis, and Vanderbilt University. Vanderbilt's contribution to this project is limited to research/lab testing. Vanderbilt will not be engaged in human research and an "Exempt" determination has been forwarded and accepted by the HRPO office.
Lay Abstract: Methicillin-resistant Staphylococcus Aureus (MRSA) is a major cause of infection in both healthcare and community settings and is one of the most common causes of healthcare-associated infections. In a cohort of 355 consecutive trauma admissions, this site has shown a 10.1% incidence of MRSA colonization by nasal swab DNA testing. Of the patients colonized, 33.3% developed an invasive MRSA infection, compared with 6% of the noncolonized patients. The colonized patients who developed invasive MRSA infections required significantly longer days of mechanical ventilation and had higher mortality. Dr Maxwell therefore hypothesize that identifying trauma patients colonized with MRSA on admission and employing decolonization regimen will reduce the incidence of invasive MRSA infection. All trauma patients admitted to the Intensive Care Unit will have nasal swabs performed to determine if they are colonized with MRSA. Patients who are colonized will be randomized to receive either decolonization treatment with Bactroban ointment applied to both nostrils and baths using antibacterial soap or they will have a placebo ointment applied to both nostrils and routine soap baths. Samples of bodily fluids will be obtained to assess for MRSA infections, based on the clinical picture. All MRSA positive cultures will then be tested to identify which strain of MRSA is causing the infection. This will be compared to the initial nasal swab to see if these are the same strain of MRSA.

Due to a recent NEJM publication, the randomization procedure of this study was removed. The revised study will evaluate decolonization of MRSA from patients admitted to the Intensive Care Unit following trauma treating them with a five day course of chlorhexidine baths and mupirocin ointment to bilateral nares. Many hospital facilities throughout this country are incorporating these treatments as standard practice for their patients. The original paradigm for this study involving the comparison of these treatments with a placebo treatment course has thus become obsolete. Additionally, the preliminary data showed only 26% of patients were decolonized following the placebo treatment while 48% were decolonized with the treatment group. More significantly, 32% of patients in the placebo group developed additional MRSA infections during their hospitalization while only 17% of the other group did. This has significant impact on the patient's length of stay, morbidity, and overall cost of hospitalization.

By evaluating the efficacy of the chlorhexidine/mupirocin treatment, it can be determined if treatment of colonized patients might decrease their systemic infection rate and this change their hospital course. The primary outcome measure of invasive MRSA infection rates remain valid; it will be just be compared between those patients who remain colonized versus those who are decolonized. The secondary endpoints of hospital length of stay, ICU length of stay, mechanical ventilation days, and mortality rate of decolonization remain similarly relevant.
Progress Reported: *HRPO Log #A-16977.4a*. HRPO approval for the lead site was obtained on 1/30/12. As of the last quarterly report, dated 8/14/13, 529 subjects have been screened with 46 subjects enrolled. Total enrollment goal is 150. Genetic specimens have been sent to Vanderbilt for testing, results are in process, Subject screening and enrollment is ongoing.

Project 6:
Project Title: Hepcidin and Anemia in Trauma
Principal Investigator: Lena M. Napolitano, MD

Lead Site: University of Michigan Health System, Ann Arbor MI

Lay Abstract: Anemia (low hemoglobin and red blood cell count) is common in trauma patients and is associated with a high rate of blood transfusion. Anemia is a problem in trauma patients, particularly in the recovery phase, since it can inhibit trauma patients from participating in physical therapy. This study is designed to determine how long anemia persists in trauma patients and why anemia does not resolve. Hepcidin, a peptide made in the liver, has recently been identified as the key regulator of iron homeostasis, and plays a major role in how and why anemia develops. Hepcidin reduces iron availability by: (1) decreased iron absorption across the intestine and (2) decreased release of iron– iron is locked in the cells and not available to make red blood cells. High levels of hepcidin induce a state of functional iron deficiency. Hepcidin is increased in states of inflammation, and likely plays an important role in the acute inflammation that occurs with trauma. However, no studies have measured hepcidin in trauma patients.

If hepcidin levels are elevated in trauma, this will confirm that inability to use iron stores is key to the anemia of trauma. Dr Napolitano suspects that hepcidin will be increased early after trauma and that anemia will not resolve in trauma until late. By measuring changes in red blood cells, hepcidin and other markers of inflammation in trauma patients she can critically examine potential therapeutic strategies for the treatment and of anemia in trauma and critical care.

Progress Reported: *HRPO Log #A-16977.8.* HRPO approval was obtained on 3/30/12. As of the last report dated 7/22/13, 407 subjects were screened with 62 subjects enrolled. Total enrollment goal is 100 subjects. An amendment to alter the consent process, to improve enrollment, is in process. This amendment is still under review at the local IRB. Subject enrollment continues.

Project 7:

Project Title: Effect of Antioxidant Vitamins on Coagulopathy and Nosocomial Pneumonia after Severe Trauma

Principal Investigator: Jean-Francois Pittet, MD

Lead Site: University of Alabama at Birmingham

Lay Abstract: This project will examine the effect of antioxidant vitamins (vitamins C and E) on patients who suffer severe trauma and have severe bleeding. Recent clinical studies have demonstrated that patients with severe bleeding from trauma do not coagulate or clot normally before they are treated. This PI has previously shown that one of the major reasons why these trauma patients do no coagulate normally is specific derangements with the protein (protein C) that normally prevents unwanted spontaneous formation of blood clot in the vessels. Antioxidant vitamins C and E have been shown to reduce mortality, organ failure and surgical site infections in trauma patients and to attenuate the procoagulant activity associated with the acute response in humans. This project proposes to determine whether the administration of a low-cost and safe therapy, i.e. antioxidant vitamins C and E, given early after severe trauma would attenuate the posttraumatic coagulation derangements and significantly decrease lung infections in trauma patients. The results obtained may help to find new treatments that may reduce the severity of bleeding and infection after trauma in humans.

Progress Reported: *HRPO Log# A-16977.6.* Approval for this project was obtained on 8/16/2012. The expectation was the project would start within the first quarter of approval. Due to various factors at the lead site, the project was significantly delayed in starting. The PI confirmed the subject enrollment was initiated on May 20, 2013. This project was discussed at the NTI Science Committee on May 16, 2013, due to lack of progress. At the time of the NTI

Science Committee meeting, subject enrollment had not been initiated. In June 2013, the PI was asked to provide an explanation in the delay of over 40 weeks from HRPO approval and study initiation. The PI stated there were several delays due to staffing changes and other issues but that all issues were now resolved and the study would proceed without interruption. The PI responded to this request and the NTI Science Committee opted to allow the study to continue with close monitoring of enrollment goals. At the next NTI Science Committee meeting on 9/11/13, a study update was provided. At that time, there were 11 subjects enrollment since the May 20, 2013 start date. This was of concern to the Science Committee, since the enrollment goal for this single center project is 700 subjects. In September the PI contacted NTI with several concerns about the lack of progress of the study. As a result of these concerns and delays, it was determined by the NTI Science Committee to terminate the study. As of the final report dated 9/13/13, 40 subjects were screened and 11 were enrolled. This project is now closed. HRPO close out documents are in process. The PI has submitted an amendment to the protocol to remove the DOD specific language from the consent and protocol. Once acknowledged by the local IRB is obtained, documents will be submitted to HRPO for review and final close out.

Project 8:

Project Title: Thrombelastography (TEG®) based dosing of enoxaparin for thromboprophylaxis: a prospective randomized trial

Principal Investigator: Martin A. Schreiber, MD

Lead Site: Oregon Health & Science University (OHSU)

Participating Sites: University of Texas Health Science Center at Houston, and University of Washington at Harborview.

Lay Abstract: The risk of developing a blood clot occurs in up to 60% of all critical care patients. Many times Lovenox is given to patients who are at a higher risk of developing clots in their legs or lungs. Recent data suggest that a standard dose of Lovenox may not fully prevent the development of these clots especially in critically ill or obese patients. Routine enoxaparin dosing can also result in bleeding complications. Thrombelastography (TEG) can be used to measure how blood clots. The purposes of this study are to: a) learn if the TEG can better guide physicians in prescribing an effective dose of Lovenox compared to standard doses in preventing blood clots from developing in the legs and lungs, b) compare the development of blood clots in patients receiving the standard dose to patients receiving a TEG guided dose of Lovenox, and c) determine if TEG guided dosing results in decreased bleeding complications compared to standard dosing. Enrolled patients will be randomized to receive the standard dose ordered by their doctor or to have their dose modified based on the TEG results. Patients will have up to 1 teaspoon of blood drawn as often as daily or as infrequently as two times a week until the medicine is stopped or until they are discharged from the hospital. We will compare incidence of blood clots formed and bleeding complications between the 2 groups of patients to determine if TEG modified dosing relates to a lower rate of blood clots in critically ill patients.

Progress Reported: *HRPO Log #A-16977.7a*. HRPO approval was obtained on 9/10/2012. As of the last report dated 10/9/13, there have been 2,904 subjects screened with 69 subjects enrolled at two of the sites (OHSU & UT Houston). University of Washington at Harborview is pending IRB approval. Once IRB approved, HRPO approval will be sought. Subject enrollment will continue.

Project 9:

Project Title: Delayed Splenic Rupture after Non-Operative Management of Blunt Splenic Injury; an American Association for the Surgery of Trauma (AAST) Multi-Institutional Prospective Trial

Principal Investigator: Ben Zarzaur, MD

Lead Site: University of Tennessee at Memphis

Participating Sites: University of California at San Diego (UCSD), University of Texas Health Science Center San Antonio (UTHSCSA), University of Pittsburgh –Mercy Hospital, University of Pittsburgh–Presbyterian Hospital; University of Texas Health Science Center at Houston (UTHSC-Houston), University of Florida Health Science Center at Jacksonville, Yale School of Medicine, Case Western Reserve, Adams Cowley Shock Trauma Center, Medical College of Wisconsin (MCW).

Lay Abstract: Nearly 39,000 adults will suffer a blunt splenic injury (BSI) this year from incidents such as car crashes and falls. Current guidelines suggest that if a patient with a BSI has a good heart rate and good blood pressure that he or she does not have to go immediately to the operating room to have the spleen removed. However, over 10% of patients managed this way will have to undergo spleen removal within 5 days of injury because the spleen will begin to severely bleed. The greater risk, though, may be to patients who are discharged from the hospital after only a few days. These patients may suffer sudden spleen rupture in the outpatient setting. The 6-month risk of spleen removal after discharge with BSI is thought to be less than 2%. But, the exact rate is not known because no one has tried to follow patients with BSI for a full 6 months after injury to determine what will happen. In this research the PI's plan to follow 1000 patients with BSI from 11 trauma centers across the country for 6 months. By doing this, the investigators will obtain an accurate estimate of the 6 month risk of spleen rupture after BSI. The investigators will also be able to determine factors associated with delayed splenic rupture. They will be able to determine which of the several treatments are best for patients with a BSI. This research will be significant because it is expected to lead to the development of strategies that will result in subjecting adults with BSI to the least risk while preserving the most spleens.

Progress Reported: Each site has obtained HRPO approval and contracting is in place. Each site is nearing completion of the 180 day follow up phase. Data listed below (Table 1) is current as of 9/28/13.

Table 1: Site status for Delayed Splenic Rupture after Non-Operative Management of Blunt Splenic Injury; an American Association for the Surgery of Trauma (AAST) Multi-Institutional Prospective Trial.

HRPO Log#	Site PI	Site	# of subjects screened	# of subjects enrolled
A-16977.3a	Ben Zarzaur, MD	UTenn Memphis	185	75
A-16977.3b	Raul Coimbra, MD	UCSD	29	6
A-16977.3c	John Myers, MD	UTHSC-San Antonio	110	54
A-16977.3d	Aaron Scifres, MD	UPitt-Mercy Hospital	18	14
A-16977.3e	Louis Alarcon, MD	UPitt-Presbyterian	50	28
A-16977.3f	Rosemary Kozar, MD	UTHSC-Houston	152	64
A-16977.3g	Andrew Kerwin, MD	Univ of Florida-Jacksonville	30	10
A-16977.3h	Adrian Maung, MD	Yale School of Medicine	56	19
A-16977.3i	Jeffrey Claridge, MD	Case Western Reserve	127	50
A-16977.3j	Thomas Scalea, MD	Adams Cowley Shock Trauma	162	33
A-16977.3k	Todd Neideen, MD	Medical College of Wisconsin	83	**30**
		Total =	1,002 screened	383 enrolled

B. The contractor will provide multiple meeting forums for progress towards methods for military-civilian transfer of medical advances, and development of clinical protocols from promising currently funded pilot studies, as determined by the Science Committee. These meetings will include military and civilian researchers.

No meetings occurred in the reporting period.

Table 2: Overall Award Milestones

Milestone	Planned Date	Actual Date	Projected Completion Date	Status
Prepare and Issue RFP	Yr1Qtr1	Yr1Qtr1	N/A	Completed
NTI Board Science Committee Review and Select Proposals for Funding	Yr1Qtr1	Yr1Qtr1	N/A	Completed
Award Grants	Yr1Qtr1	Yr1Qtr1	N/A	Completed
Contract with Awardee Organization	Yr1Qtr1	Ongoing	Term of the Contract	Ongoing; 19 of 19 complete
Manage Compliance of Awards	Ongoing	Ongoing	Term of the Contract	Ongoing
Provide meeting forums	Ongoing	Ongoing	Yr2Qtr4	Ongoing

KEY RESEARCH ACCOMPLISHMENTS

None at this time

REPORTABLE OUTCOMES

None at this time

CONCLUSION

NTI has successfully completed a RFP, peer-reviewed process, with selection of nine relevant trauma projects. We are conducting on-going oversight of each project under this award. Each of the funded projects is of critical importance in the advancement of trauma care. Traumatic injury, hemorrhage and ongoing management of the trauma patient with infection, anemia, and bleeding complications have the potential to have a long lasting impact on outcomes for trauma patients.

NTI continues to seek opportunities to provide meetings for progress towards methods for military-civilian transfer of medical advances, and development of clinical protocols from promising currently funded pilot studies, as determined by the Science Committee.

ABBREVIATIONS

AAST	American Association for the Surgery of Trauma
ALI	Acute lung injury
ALIVE	Acute Lung Injury Ventilation Evaluation
APRV	airway pressure release ventilation
ARDSNet	Acute Respiratory Distress Syndrome Network
BMC	Boston Medical Center
BSI	Blunt Splenic Injury
CT	computed tomography
DNA	Deoxyribonucleic acid
EHS	Erlanger Health System
FWB	Fresh Whole Blood
HRPO	Human Research Protection Office
HSPS	Human Subjects Protection Scientists
ICD	International Classification of Diseases
ICU	Intensive Care Unit
IRB	Institutional Review Board
MCW	Medical College of Wisconsin
MRSA	Methicillin-resistant Staphylococcus aureus
NTI	National Trauma Institute
OHSU	Oregon Health & Science University
OR	Operating Room
PI	Principal Investigator
RBCs	Red Blood Cells
RFP	Request for Proposal
SAMMC	San Antonio Military Medical Center
SOM	School of Medicine
TEG	Thrombelastography
UTHSC	University of Tennessee Health Science Center
UTHSC-Houston	University of Texas Health Science Center at Houston
UTHSCSA	University of Texas Health Science Center at San Antonio
UCLA	University of California, Los Angeles
UCSD	University of California, San Diego
UCSF	University of California, San Francisco
UPitt	University of Pittsburgh
USAISR	United States Army Institute of Surgical Research

Reset Form

FEDERAL FINANCIAL REPORT

(Follow form instructions)

1. Federal Agency and Organizational Element to Which Report is Submitted	2. Federal Grant or Other Identifying Number Assigned by Federal Agency (To report multiple grants, use FFR Attachment)	Page	of
DOD, USAMRAA	W81XWH-11-1-0841	1	1 pages

3. Recipient Organization (Name and complete address including Zip code)

National Trauma Institute, 8000 IH 10 W, Suite 600, San Antonio, Texas, 78230

4a. DUNS Number	4b. EIN	5. Recipient Account Number or Identifying Number (To report multiple grants, use FFR Attachment)	6. Report Type	7. Basis of Accounting
800219185	32-0170279		☐ Quarterly ☐ Semi-Annual ☐ Annual ☐ Final	☐ Cash ☒ Accrual

8. Project/Grant Period From: (Month, Day, Year)	To: (Month, Day, Year)	9. Reporting Period End Date (Month, Day, Year)
09/29/2011	03/28/2014	09/30/2013

10. **Transactions**	Cumulative
(Use lines a-c for single or multiple grant reporting)	
Federal Cash (To report multiple grants, also use FFR Attachment):	
a. Cash Receipts	$3,845,000
b. Cash Disbursements	$1,965,159
c. Cash on Hand (line a minus b)	$1,879,841
(Use lines d-o for single grant reporting)	
Federal Expenditures and Unobligated Balance:	
d. Total Federal funds authorized	$3,845,000
e. Federal share of expenditures	$1,965,159
f. Federal share of unliquidated obligations	$1,743,657
g. Total Federal share (sum of lines e and f)	$3,708,816
h. Unobligated balance of Federal funds (line d minus g)	$136,184
Recipient Share:	
i. Total recipient share required	
j. Recipient share of expenditures	
k. Remaining recipient share to be provided (line i minus j)	
Program Income:	
l. Total Federal program income earned	
m. Program income expended in accordance with the deduction alternative	677
n. Program income expended in accordance with the addition alternative	
o. Unexpended program income (line l minus line m or line n)	

11. Indirect Expense	a. Type	b. Rate	c. Period From	Period To	d. Base	e. Amount Charged	f. Federal Share
	Provisional	25%	9/29/11	6/30/2013	$1,587,411	$332,713	$332,713
				g. Totals:	$1,587,411	$332,713	$332,713

12. *Remarks: Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation:*

13. Certification: By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and intent set forth in the award documents. I am aware that any false, fictitious, or fraudulent information may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

a. Typed or Printed Name and Title of Authorized Certifying Official	c. Telephone (Area code, number and extension)
Monica Phillips, Director of Operations	210-524-7739
	d. Email address: monica.phillips@nationaltraumainstitute.org
b. Signature of Authorized Certifying Official: Monica Phillips	e. Date Report Submitted (Month, Day, Year): 10/28/2013
	14. Agency use only:

Standard Form 425 - Revised 6/28/2010
OMB Approval Number: 0348-0061
Expiration Date: 10/31/2011

Paperwork Burden Statement

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is 0348-0061. Public reporting burden for this collection of information is estimated to average 1.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0061), Washington, DC 20503.

REPORT OF INVENTIONS AND SUBCONTRACTS

(Pursuant to "Patent Rights" Contract Clause) (See Instructions on back)

Form Approved
OMB No. 0000-0096
Expires Jun 31, 2008

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE ABOVE ORGANIZATION. RETURN COMPLETED FORM TO THE CONTRACTING OFFICER.

1.a. NAME OF CONTRACTOR/SUBCONTRACTOR	c. CONTRACT NUMBER	2.a. NAME OF GOVERNMENT PRIME CONTRACTOR	c. CONTRACT NUMBER	3. TYPE OF REPORT (X one)
National Trauma Institute	W81XWH-11-1-0841	same		X a. INTERIM ☐ b. FINAL

b. ADDRESS (Include ZIP Code)	d. AWARD DATE (YYYYMMDD)	b. ADDRESS (Include ZIP Code)	c. AWARD DATE (YYYYMMDD)	4. REPORTING PERIOD (YYYYMMDD)
8000 III 10 West, Suite 600 San Antonio, TX 78230	20110929	same		a. FROM 20120929 b. TO 20130928

SECTION I - SUBJECT INVENTIONS

5. "SUBJECT INVENTIONS" REQUIRED TO BE REPORTED BY CONTRACTOR/SUBCONTRACTOR (If "None," so state)

NAME(S) OF INVENTOR(S) (Last, First, Middle Initial) a.	TITLE OF INVENTION(S) b.	DISCLOSURE NUMBER, PATENT APPLICATION SERIAL NUMBER OR PATENT NUMBER c.	ELECTION TO FILE PATENT APPLICATIONS (X) d.				CONFIRMATORY INSTRUMENT OR ASSIGNMENT FORWARDED TO CONTRACTING OFFICER (X) e.	
			(1) UNITED STATES		(2) FOREIGN			
			(a) YES	(b) NO	(a) YES	(b) NO	(a) YES	(b) NO

f. EMPLOYER OF INVENTOR(S) NOT EMPLOYED BY CONTRACTOR/SUBCONTRACTOR		g. ELECTED FOREIGN COUNTRIES IN WHICH A PATENT APPLICATION WILL BE FILED	
(1) (a) NAME OF INVENTOR (Last, First, Middle Initial)	(2) (a) NAME OF INVENTOR (Last, First, Middle Initial)	(1) TITLE OF INVENTION	(2) FOREIGN COUNTRIES OF PATENT APPLICATION
(b) NAME OF EMPLOYER	(b) NAME OF EMPLOYER		
(c) ADDRESS OF EMPLOYER (Include ZIP Code)	(c) ADDRESS OF EMPLOYER (Include ZIP Code)		

SECTION II - SUBCONTRACTS (Containing a "Patent Rights" clause)

6. SUBCONTRACTS AWARDED BY CONTRACTOR/SUBCONTRACTOR (If "None," so state)

NAME OF SUBCONTRACTOR(S) a.	ADDRESS (Include ZIP Code) b.	SUBCONTRACT NUMBER(S) c.	FAR "PATENT RIGHTS" d.		DESCRIPTION OF WORK TO BE PERFORMED UNDER SUBCONTRACT(S) e.	SUBCONTRACT DATES (YYYYMMDD) f.	
			(1) CLAUSE NUMBER	(2) DATE (YYYYMM)		(1) AWARD	(2) ESTIMATED COMPLETION
University of Tennessee Health Science Center	910 Madison Avenue, 2nd floor Memphis, TN 38613	NCH-10-020a			Medical research: Delayed splenic rupture after non-operative management	20110929	20140328
University of California San Diego	200 W. Arbor Drive 8220 La Jolla, CA 92103-8220	NCH-10-020b			Medical research: Delayed splenic rupture after non-operative management	20110929	20131116

SECTION III - CERTIFICATION

7. CERTIFICATION OF REPORT BY CONTRACTOR/SUBCONTRACTOR (Not required if "X" as appropriate)

☐ SMALL BUSINESS or X NONPROFIT ORGANIZATION

I certify that the reporting party has procedures for prompt identification and timely disclosure of "Subject Inventions," that such procedures have been followed and that all "Subject Inventions" have been reported.

a. NAME OF AUTHORIZED CONTRACTOR/SUBCONTRACTOR OFFICIAL (Last, First, Middle Initial)	b. TITLE	c. SIGNATURE	d. DATE SIGNED

DD882 Form – Continuation

6a. Name	b. Address	c. Subcontract number	d. (1) clause number	d.(2) date	e. Description of work to be performed under subcontracts	f.(1) award dates	f.(2) estimated completion
University of Texas Health Science Center at San Antonio	7703 Floyd Curl Drive, MC 7740, San Antonio, TX 78229-3900	NCH-10-020c			Medical research: Delayed splenic rupture after non-operative management	20110929	20130928
University of Pittsburgh	123 University Place, Lower Level, Pittsburgh, PA 15213	NCH-10-020d			Medical research: Delayed splenic rupture after non-operative management	20120529	20131201
University of Pittsburgh	123 University Place, Lower Level, Pittsburgh, PA 15213	NCH-10-020e			Medical research: Delayed splenic rupture after non-operative management	20130126	20131201
University of Texas Health Science Center	7000 Fannin, Suite 1006, Houston TX 77030	NCH-10-020f			Medical research: Delayed splenic rupture after non-operative management	20120130	20130831
University of Florida Board of Trustees	210 Grinter Hall PO Box 115500, Gainesville, FL 32615500	NCH-10-020g			Medical research: Delayed splenic rupture after non-operative management	20120315	20131231
Yale University	47 College Street, Ste 203, New Haven, CT 06520-0847	NCH-10-020h			Medical research: Delayed splenic rupture after non-operative management	20120109	20131231
Medical College of Wisconsin	8701 Watertown Plank Road, Milaukee, WI 53226-0509	NCH-10-020k			Medical research: Delayed splenic rupture after non-operative management	20120327	20131231
The MetroHealth System	2500 MetroHealth Drive, Cleveland, OH 44109-1900	NCH-10-020i			Medical research: Delayed splenic rupture after non-operative management	20120214	20131231
University of Maryland Baltimore	620 Lexington Street, 4th floor, Baltimore, MD 21201	NCH-10-020j			Medical research: Delayed splenic rupture after non-operative management	20120214	20131231

6a. Name	b. Address	c. Subcontract number	d. (1) clause number	d.(2) date	e. Description of work to be performed under subcontracts	f.(1) award dates	f.(2) estimated completion
Christiana Care Health Services	4755 Ogletown-Stanton Road, Newark, DE 19718-0002	NTI-10-011			Medical research: the safety and efficacy of platelet transfusion in patients receiving antiplatelet therapy that sustain intracranial hemorrhage	20120404	20130703
University of Alabama at Birmingham	1702 2nd Ave. South AB 1120 35294-0111, Birmingham, AL 35294	NCH-10-013			Medical research: Effect of antioxidant vitamins on coagulopathy and nosocomial pneumonia after severer trauma	20120816	20130913
University of California San Diego	200 W. Arbor Drive #8896, San Diego, CA 92103-8896	NCH-10-016			Medical research: Detection and management of non-compressible hemorrhage by vena cava ultrasonography	20111117	20131116
The Regents of the University of California	1100 Kinross Avenue, Suite 211, Los Angeles, CA 90095-1406	NCH-10-033			Medical research: Transfusion of stored fresh whole blood in a civilian trauma center	20120306	20130905
University of Tennessee	62 S. Dunlap, Suite 300, Memphis TN 38163	TRA-10-020			Medical research: Acute lung injury ventilation evaluation (ALIVE) trial	20130805	20140328
Oregon Health & Science University	3181 SW Sam Jackson Park Road, L611, Portland, OR 97239	NCH-10-053			Medical research: Thromboelastography (TEG) based dosing of enoxaparin for thromboprophylaxis	20120910	20140328
The Regents of the University of Michigan	1068 Wolverine Tower, 303 South State Street, Ann Arbor, MI 48109-1274	TRA-10-037			Medical research: Hepcidin and anemia in trauma	20120330	20140328
University of Pittsburgh	123 University Place, Lower Level, Pittsburgh, PA 15213	TRA-10-020			Medical research: Characterization of the effects of early sex-hormone environment following injury	20120701	20130630